510(k) Summary

OCT 20 2010

Submitted by:

Future Mobility HealthCare Inc.
3223 Orlando Drive
Mississauga, ON, L4V 1C5
Tel. (1-888-737-4011)

Contact:

Mr. Abdul Panchbhaya
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Date: July 7, 2010

Trade Name: Galaxy Lite Folding mechanical wheelchair

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Predicate Devices:

LEGALLY MARKETED PREDICATE DEVICES	MANUFACTURER NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
Quickie 2 HP	Motion Design Inc (Sunrise Medical Design Inc)	Class I/IOR	K890050
Stellato	Future Mobility Healthcare, In.	Class I/IOR	K061010

The rational of declaring the Future Mobility Healthcare Galaxy Lite is substantially equivalent to the above predicate devices is based on the following:

- ✓ Same Indications for use: providing mobility to persons limited to a sitting position.
- ✓ Similar key design technical characteristics- The Quickie 2 HP, Stellato and Galaxy Lite are mechanical wheelchairs which have technical similarities. The Quickie 2 HP and Galaxy Lite contain an adjustable rear wheel location and provide similar performance.
- ✓ The Quickie 2 HP, Stellato and Galaxy Lite folding wheelchairs are manually operated, self propelled mechanical wheelchairs, and may also be used as attendant propelled transport devices. They consist of folding mechanical aluminum frames for use by patients weighing up to 250 lbs.

Conclusion:
Future Mobility HealthCare Galaxy Lite folding mechanical wheelchair was developed in accordance with ISO 7176, parts 1, 5, 7, 8 and 11. It is the conclusion that the Future Mobility HealthCare Galaxy Lite is safe and effective, as well as substantially equivalent to the legally marketed device identified as the predicate devices identified as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Future Mobility HealthCare Inc.
% Mr. Abdul Panchbhaya
President & CEO
3223 Orlando Drive
Mississauga, Ontario
Canada L4V 1C5

OCT 20 2010

Re: K102031
Trade/Device Name: Future Mobility Healthcare Inc. Galaxy Lite
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 3, 2010
Received: September 3, 2010

Dear Mr. Panchbhaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K102031

OCT 20 2010

Device Name: Future Mobility Healthcare Inc. Galaxy Lite

Indication for Use:

The Future Mobility Healthcare Inc. Galaxy Lite Wheelchair is intended to provide mobility to persons limited to a sitting position.

Prescription Use_____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Devise Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102031